JUN 2 - 2005

510 (k) SUMMARY K050738

This 510(k) summary of safety and effectivness is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidence concerning the organization and content of a 510(k) summary.

FiberTech's USA Fiber Optic Delivery System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitted by:

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Germany
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Contact Person: Armin Kaus, Ph.D.

Date Prepared: March 8, 2005

Name of Device and Name

FT Fiber Optic Delivery Systems

Common or Usual Name

Nd: YAG Laser Fiber Optic Delivery System;
Ho: YAG Laser Fiber Optic Delivery System;
KTP Laser Fiber Optic Delivery System;
Diode Laser Fiber Optic Delivery System

Classification Name

Accessory to laser Surgical Instruments, Class II in accordance with 21 C.F.R. § 878.4810.
The product code for the devices are **GEX**.

Predicate Devices

Ceramoptec's Fiber Optic Delivery Sytems incl. Handpieces (K923953, K943445, K942182 and K951775),
Coherent's Fiber Optic Delivery System incl. Handpieces (K960413, K960032 and K991258)
InnovaQuartz Fiber Optic Delivery System (K994010),
Laser Peripherals Fiber Optic Delivery System (K92272, K011207 and K030959),
Trymedyne Inc., Fiber Optic Delivery System (K973172)

Intend of Use

The Laser peripherals bare laser fibers, ENT fibers and Endoprobes are intended for use in laser surgical procedure for cutting, coagulating, or vaporizing in any soft tissue application for which compatible Nd: YAG, Ho: YAG, KTP and Diode lasers have been cleared.

Technological Characteristics and Substancial Equivalence

Fiber Optic Delivery Systems and Handpieces are intended to vaporize, coagulate, incise and excise tissue and which are designed for any indication for which compatible laser systems have been cleared by FDA. Similarly, the predicate devices are also components of delivery systems designed to deliver laser radiation to a specified point.

Second, FiberTech's Fiber Optic Delivery System's fiber optical Handpiece and Tip has a similar material composition as its predicate devices. Third, the Fiber Optic Delivery System is available in sizes between 200 micron and 1000 micron.Ceramoptec's and Coherent Laser Delivery Systems is available also in sizes ranging from 200 micron to 1000 micron.

Fourth, the reusable and the disposable Fiber Optic Delivery Systems are available in the same tip shapes and handpiece configurations. Further, both the reusable and the disposable devices are prepackaged sterile and fit lasers which employ SMA 905 connectors or lasers which have suitable adapters to allow SMA 905 connectors to be used.

Finally, the reusable Fiber Optic Delivery System can be reused only once the optical fiber tip is properly cleaned, inspected, stripped and cleaved.
In sum, there are more or less no differences between the reusalbe and disposable fiber optic systems whith their predicate devices. Although these differences are so extremly minor there are no new questions of safety and effectiveness raised by the indroduction of this devices.

Performance Data

All of the Fiber Optic Delivery Systems are CE marked in accordance with the Medical Device Directive 93/42/EEC Annex II, Article 3. (Registration No: HD 2111863 01, Report No: C 2113751 E 02) and are also certified under the requirements specified in EN ISO 13485:2003 (Registration No: SX 60008740 0001) and certified for Quality Management System according to EN ISO 9001:2000 (Registration No: SY 60008739 0001)

Signed: _____

Armin Kaus, Ph.D.
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 - 2005

Armin Kaus, Ph.D.
President/CEO
FiberTech GMBH
4111 E. Valley Auto Drive, Suite 104
Mesa, Arizona 85206

Re: K050738
Trade/Device Name: FT Fiber Optic Delivery Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 11, 2005
Received: April 18, 2005

Dear Dr. Kaus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K050738**

Device Name: **FT Fiber Optic Delivery Systems**

Indications For Use: The Laser peripherals bare laser fibers, ENT fibers and Endoprobes are intended for use in laser surgical procedure for cutting, coagulating, or vaporizing in any soft tissue application for which compatible Nd: YAG, Ho: YAG, KTP and Diode lasers have been cleared.

Prescription Use ✓ OR Over-The-Counter Use_____

Please do not right below this line – continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Dental, Restorative and Physiological Devices

K050738